

REMARKS

Claims 1-114 are pending, with claims 8-9, 17-19, 44-45, 51, 60-61, 67-81, 89-90, 97-98, 101, 106, and 108-112 having previously been withdrawn without prejudice. No claims are amended or canceled hereby. In the present non-final Office Action, Examiner has provided a new grounds of rejection. In this regard, Examiner has maintained her previous rejections of the non-withdrawn claims based on Alden and Hagen, and in some of the claims, Simpson. Examiner has also now rejected those same claims under 35 U.S.C. § 103(a) on the basis of Gordon U.S. Patent No. 4,673,386 ("Gordon") in view of Alden and in further view of Hagen. Applicants respectfully traverse the rejection of the claims. In this response, we first address the new grounds of rejection based on the combination of Gordon, Alden and Hagen, and then turn our attention to the rejections based on Alden and Hagen, alone or in further combination with Simpson.

Rejection of claims based on Gordon, Alden, and Hagen

In an attempt to make out a *prima facie* case of obviousness, Examiner has relied on a number of unwarranted assumptions. A *prima facie* case of obviousness is satisfied if there is an apparent reason to modify the prior art references flowing from either the references, the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved, and the results are expected. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007). In the instant case, Examiner relies on modifying Gordon according to the teaching of Alden, and then modifying this asserted combination according to the teaching of Hagen. Applicants respectfully submit, however, that the asserted combination of these references fails to meet Examiner's burden. In this regard,

Examiner has impermissibly used Applicant's present invention as a roadmap or blueprint for presumably cobbling together bits and pieces of the prior art in order to reach the claims. The result is an obviousness rejection premised on speculative prior art combinations that, as a matter of law, must not stand.

Examiner's primary reference is Gordon, which has been of record from the beginning of prosecution but only applied in the most recent Office Action. Gordon is directed to a closed blood sampling system having a reservoir for pulling back fluid in a fluid control line so as to collect a whole blood sample at a sample site disposed in the fluid line. The fluid in the reservoir is then restored to the fluid line (and thus to the patient) after the whole blood sample has been drawn. As explained in the Background section of the present application, Gordon's reservoir is an in-line type of reservoir having a piston/cylinder arrangement. The reservoir includes a housing having inlet and outlet ports coupled into the tubing of the closed blood sampling system and a variable volume chamber disposed therein. In this regard, the housing includes a rigid wall comprised of a bottom and a side which define a cylinder having an oval cross section that receives an oval-shaped piston through an upper opening of the cylinder so that a rigid face wall of the piston confronts the cylinder bottom to define the variable volume chamber therebetween. The piston is movable toward and away from the rigid bottom of the cylinder wall so as to increase and decrease the interior volume of the chamber. The piston has a minimum volume position with the rigid face of the piston adjacent the bottom of the cylinder. As the piston is pulled away from the bottom, a negative pressure is created that pulls blood (and any fluid downstream of the reservoir) away from the patient, through the tubing, and toward the reservoir. Movement of the piston back

toward the bottom discharges fluid in the chamber back through the tubing and toward the patient.

As she must, Examiner acknowledges that "Gordon does not disclose a flexible membrane overlying at least a part of the rigid wall to define the variable volume chamber." Office Action, p. 3. To fill this void, and in the first step of Examiner's obviousness rejection, Examiner asserts that Alden discloses such a flexible membrane and that it would have been obvious "to replace the piston in the reservoir of Gordon with a flexible membrane overlying at least part of the rigid wall to define the variable volume chamber as taught by Alden et al as an equally effective means to control the flow of blood into and out of the reservoir." *Id.* at p. 4. Examiner, however, provides absolutely no evidence to support the asserted modification of the reservoir of Gordon using the flexible membrane of Alden. Again, a *prima facie* case of obviousness requires an apparent reason to modify a reference flowing from either the reference itself, the knowledge of those having skill in the art, or the problem to be solved. *KSR*, 127 S. Ct. at 1740. There is no evidence proffered by Examiner for the notion that the piston of Gordon may be readily interchanged with the flexible membrane of Alden.

As an initial matter the disclosures of Gordon and Alden provide no evidence as to why the piston should be replaced with a flexible membrane. Quite to the contrary, Gordon, for example, emphasizes that the piston is rigid. In this regard, in the Summary section, Gordon unequivocally states "[t]he pump sealing member is further provided with a rigid lower surface to permit contact with the fluid within the chamber without attenuating the pressure of that fluid." Col. 2, ll. 17-20. Likewise in the Detailed Description of the Presently Preferred Embodiment section, Gordon unequivocally states:

Sealing member 23 is further provided with a rigid lower surface 24 which directly contacts the fluid passing through the mechanism 11. The lower surface 24 is formed such that, when sealing member 23 is seated upon piston 15, the rigid surface 24 is not displaceably (sic) to attenuate or otherwise alter the pressure of fluid passing through the arterial line 40.

Col. 3, l. 63-Col. 4, l. 2. Thus, Applicants submit that there is an explicit teaching away from the asserted modification of Gordon by replacing the (rigid bottom) piston with a flexible membrane. Examiner cannot pick and choose what she likes to fill in her roadmap, while ignoring the express teachings away from the claimed invention. *W.L. Gore and Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983) (noting that a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention).

There may be very good reasons that Gordon emphasizes a rigid bottom wall to the piston so as not to attenuate or otherwise alter the pressure of the fluid in the fluid line. For example, Applicants submit that the Examiner's modification of replacing the piston with a flexible membrane would destroy the intended purpose of Gordon, thus destroying Examiner's obviousness rejection. *In re Gordon*, 733 F.3d 900, 902 (Fed. Cir. 1984) (a reference teaches away from proposed modifications that render the disclosed invention inoperable for its intended purpose). In this regard, one purpose of a closed blood sampling system is to combine a blood pressure monitoring function with a blood withdrawal or fluid infusion function. As illustrated in Fig. 2 of Gordon, the closed blood sampling system includes a pressure transducer (43) just upstream from the reservoir (11) so as to sense the pressure in the fluid line (and thus the blood pressure of the patient). Thus, to get an accurate reading of the patient's blood pressure, the reservoir should not affect the fluid pressure in the line. Such attenuation or altering of the fluid pressure not

only provides inaccurate blood pressure readings, such variations may negatively impact the functioning of the pressure transducer such that it has to be re-calibrated so as to provide an accurate blood pressure monitoring function. Indeed, without the piston, there is nothing to hold the flexible membrane, so the membrane can flex, even wildly and unpredictably, such that reliable pressure readings may simply not be possible (hence, why Examiner must resort to Hagen to replace the Gordon piston she proposes to remove by reference to Alden; as explained below, that further modification is inapt as well). Accordingly, not only does Gordon teach away from the Examiner's asserted modification, but Applicants submit that for those same reasons, the suggested modification would likely render the closed blood sampling system inoperable for its intended purpose. Thus, the obviousness rejection is in error and cannot stand.

Still further, the modification of replacing the piston in Gordon with the flexible membrane of Alden represents a major shift in the principle of operation of the reservoir. *In re Ratti*, 270 F.2d 810 (CCPA 1959) (If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the reference are not sufficient to render the claims *prima facie* obvious). In this regard, Gordon's piston/cylinder arrangement provides for an active-pull device for drawing fluid into the reservoir. This is achieved by moving a wall of the chamber (e.g., the piston) in whole body movement. As the piston is pulled away from the cylinder bottom to expand the variable volume chamber, negative pressure is forcibly created that strongly pulls fluid back toward the reservoir. In other words, the system is rather rigid and has substantially no give, such that if the piston is pulled back too quickly, the negative pressure may be sufficient to collapse the

patient's artery. This is in contrast to the principle on which a flexible membrane based reservoir operates. The flexible membrane system provides a passive-pull device for drawing fluid into the reservoir. This is achieved by flexing a wall of the chamber (e.g., the membrane). Flexing the membrane away from the bottom of the rigid wall creates a gentler negative pressure and further provides some give that prevents or reduces the likelihood of collapsing the artery of the patient. Thus, modifying Gordon from an active-pull system to a passive-pull system is not an insignificant substitution, but represents a change in the fundamental principle on which the reservoir operates. Accordingly, for this further reason, Examiner's assertion that it would have been obvious to modify Gordon in view of Alden is in error.

The flaw in the Gordon/Alden combination becomes even more evident upon application of the third reference, Hagen, so as to reach the claims. In this regard, Hagen is applied so as to effectively undue part of the aftermath of the Gordon/Alden combination. More particularly, after combining Gordon and Alden, Examiner realizes that the asserted combination is missing a drive surface as recited in the claims. The Examiner cures this deficiency purportedly with the teaching of Hagen. Office Action, at 4 ("it would have been obvious to one of ordinary skill in the art to modify the reservoir of Gordon as modified by Alden et al to include a drive surface in the form of a movable plunger..., as taught by Hagen et al"). In essence, after having already removed the piston of Gordon and replaced it with the flexible membrane of Alden, Examiner then has to reintroduce Gordon's piston based on the piston disclosed in Hagen. This remove/replace aspect exemplified by this further combination is indicative of a pick and choose approach using Applicants invention as a roadmap.

Hagen is directed to an infusion pump having a housing defining an internal chamber and a piston disposed therein. A cap closes off the internal chamber and a spring is disposed between the cap and the back surface of the piston to apply a downward bias on the piston. The face of the piston is covered by a flexible diaphragm which is coupled to the piston along the periphery thereof. The face of the piston includes a convex region that defines an enclosed region between the piston face and the flexible diaphragm. During use, fluid pressure causes the flexible diaphragm to deform into the enclosed region as the piston moves downward. When the downward motion of the piston is stopped, the flexible diaphragm slowly deforms back to its original shape and thus continues to dispense a small amount of fluid from the infusion pump.

Even assuming for sake of argument it were appropriate to modify the Gordon/Alden combination by the teaching of Hagen, such a modification based on the teaching of Hagen would essentially result in the flexible membrane in the Gordon/Alden combination being positioned on the front face of a piston and carried thereby. Hagen clearly teaches that the flexible diaphragm is carried by and secured along the periphery of the piston. See col. 9, l. 66-col. 10, l. 4. Examiner completely ignores this teaching and instead selectively picks only the piston and flexible membrane features, without consideration to the whole teaching, to assert that it would have been obvious to provide a drive surface to the flexible membrane in the Gordon/Alden combination. Such a selective construction, however, is impermissible.

At a bare minimum, a proper modification of the flexible membrane in the Gordon/Alden combination based on Hagen would include coupling the flexible membrane to the piston so as to be carried thereby. This effectively results in the original

device of Gordon, but for the sealing member in Gordon being replaced with a flexible membrane. Notably, however, such a proper modification of Gordon/Alden based on Hagen does not result in the claimed reservoir. Examiner overcomes this weakness in the obviousness analysis by dispensing with that aspect of Hagen and only focusing in on the flexible diaphragm and piston without regard for the whole teaching of Hagen.

For the above reasons, the obviousness rejection of the claims based on the asserted combination of Gordon, Alden and Hagen is in error and the rejection cannot stand. In short, without the benefit of Applicant's disclosure, one of ordinary skill in the art would not have made the modifications as suggested by Examiner in the Office Action. Such hindsight reconstruction is impermissible and fatal to a § 103 rejection. See *W.L. Gore*, 721 F.2d ("It is difficult but necessary that the decisionmaker forget what he or she has been taught...about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art."); MPEP § 2145. Accordingly, Applicants respectfully submit that the obviousness rejection over the combination of Gordon, Alden and Hagen is in error and should be withdrawn.

Rejection of claims based on Alden and Hagen (and Simpson for certain claims)

Examiner and Applicants have discussed these references in detail in prior responses and interviews and thus a discussion of the teaching of these references will be omitted. Applicants have previously focused on the fundamental operation of their reservoir relative that that in Alden (e.g., bidirectional flow, port locations relative to chamber, etc.) without success. Nevertheless, Applicants continue to believe that

Applicants' reservoir is fundamentally different than Alden, not only in structure, but in operation. Thus, for purposes of appeal, Applicants reassert the previous arguments in the prior responses to distinguish over Alden.

Nevertheless, Applicants make further arguments herein to distinguish their claimed reservoir over that of Alden. In this regard, each of the non-withdrawn independent claims recites that the flexible membrane has a minimum volume position at which fluid still flows between the inlet port and exit port through the chamber. For example, claims 1, 38, 58, 82, 113, and 114 recite "the flexible membrane having [note that claims 58 and 114 have "with" instead] a minimum volume position spaced closely adjacent the rigid wall to define a minimum volume at which fluid still flows between the inlet port and the exit port through the chamber"; claim 95 recites "the flexible membrane having a minimum volume position with at least a portion of the lower surface of the membrane engaging the rigid wall to define a minimum volume at which fluid still flows between the inlet port and the exit port through the chamber"; and claim 103 recites "the flexible membrane having a minimum volume position closing off the open top of the channel without interfering flow between the inlet port and the exit port through the chamber." Thus, according to the express language of the claims, there is a minimum volume position at which fluid flows between the inlet port and exit port through the chamber.

The reservoir in Alden does not have any such flow between the "inlet port" (304) and the "exit port" (312) when the diaphragm (310) is in a minimum volume position (presumably shown in Fig. 3 of Alden). Were one to accept Examiner's contorted view that 304 and 312 are the claimed "inlet port" and "exit port," then the

device of Alden cannot meet the claims for there could be no flow "through the chamber" between those ports in a minimum volume position. Indeed, with those aspects so-defined, flow is precluded between the inlet port and exit port through the chamber in a minimum volume position.

Alden teaches valve (312) between the capillary channel (304) and the chamber (300). Ignoring that Alden describes valve (312) as a "check valve"¹ and treating it as a multi-positional valve (which we believe is improper for reasons provided in earlier responses), the valve will either: i) provide an opening between capillary channel (304) and chamber (300) and close off alternate exit (318); or ii) provide an opening between the chamber (300) and alternate exit (318) and close off capillary channel (304). In either scenario, in the position of the diaphragm (310) shown in Fig. 3 (e.g., minimum volume position), there can be no flow between the "inlet port" and "exit port" through the chamber.

Taking Examiner's rational one more step and, for sake of argument, assuming that the "check valve" (312) can be open such that the capillary channel (304), chamber (300), and alternate exit (318) are all in simultaneous fluid communication, Alden still fails to teach flow between the inlet port and exit port through the chamber when the diaphragm is in a minimum volume position. The reason for this is that in Alden, the "inlet port" and "exit port" communicate with the chamber via the same

¹ In the Response to Arguments, Examiner states that "regardless of the use of the term 'check valve,' Alden et al still disclose said valve used to control flow into and out of the chamber, i.e., bidirectional flow. Reliance upon an explicit disclosure in a reference is stronger than the supposedly known definition of one word in the same disclosure." Office Action, p. 15. That is an outrageous position. The term "check valve" has been understood for generations to be a one-way valve. Examiner's reliance on a clearly non-enabling, fleeting mention of a bidirectional flow is inappropriate. Nor has she provided any evidence to support her position that the well accepted meaning of the term, and the one which is actually relied upon throughout Alden for that device to function, may be so readily discarded. Even so, Alden fails to support the rejection for reasons explained in the main text.

conduit line. Consequently, when everything is open, fluid coming in capillary channel (304) will immediately exit through alternate exit (318) and completely bypass the chamber (300). Thus, there can be no flow between the inlet and exit ports and "through the chamber" as recited in the claims.

For at least the foregoing reasons, Applicants submit that the non-withdrawn independent claims, and therefore the claims which depend therefrom, define over Alden. Moreover, Hagen, which is directed to an infusion pump having but one port (14) and which was relied on merely for the proposition of a drive surface for the flexible membrane, fails to cure the deficiency in Alden. The further combination with Simpson, which was relied on for the claims directed to the closed blood sampling system, likewise fails to cure the deficiency in Alden. Accordingly, Applicants respectfully submit that the claims are allowable and that the rejections be withdrawn.

Furthermore, because generic claims 1 and 113 are allowable, Applicants respectfully request that the Examiner bring back the withdrawn claims previously restricted out of the case. Some of the withdrawn claims depend from non-withdrawn allowable independent claims and are therefore allowable for reasons provided above. The remaining withdrawn claims are either independent withdrawn claims or depend therefrom. Notable, independent claims 67 also recites "the flexible membrane having a minimum volume position spaced closely adjacent the rigid wall to define a minimum volume at which fluid still flows between the inlet port and the exit port through the chamber." Accordingly, upon bringing this independent claim back into the case, claim 67 and its dependent claims are submitted to be allowable as well.

CONCLUSION

In view of the foregoing, it is respectfully submitted that the rejections have been overcome and the case is now in condition for allowance. Accordingly, a formal Notice of Allowance is solicited at the earliest possible time.

If, for any reason, the foregoing does not place this case in condition for allowance, or if any questions remain, Examiner is respectfully requested to telephone undersigned attorney in an effort to promptly resolve same.

No fee is believed due for this paper other than that for a two-month extension of time, which fee is being submitted concurrently herewith. If any other fee is due, please take this as authorization to charge same to our Deposit Account 23-3000.

Respectfully submitted,
WOOD, HERRON & EVANS, L.L.P.

By: /kurt l grossman/
Kurt L. Grossman, Reg. No. 29,799

411 Vine Street
2700 Carew Tower
Cincinnati, OH 45202
(513) 241-2324
(513) 241-6234 (fax)